510(k) Summary

K072204

OCT 5 ° 2007

Submitter information

Contact person: Philip Liu
Manager, Regulatory Affairs & Compliance

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Date summary prepared: August 2, 2007

Device Trade or Proprietary Name: ADVIA® Chemistry Microalbumin Calibrators
ADVIA® Chemistry Microalbumin_2 Calibrators

Device Common/Usual Name or Classification Name: Calibrator

Classification Number/Class: JIX / Class II

Classification Panel: Clinical Chemistry (75)

This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92.

The assigned 510(k) number is: ____k072204_____

Predicate Device:

Device Name	DCL Microalbumin Multi-Calibrator Set
Common name	Microalbumin Calibrator
510(k) Number	k042243
Manufacturer	Diagnostic Chemicals Limited

Device Description:

The ADVIA® Chemistry Microalbumin Calibrators and ADVIA® Chemistry Microalbumin_2 Calibrators are each 5 level liquid aqueous buffered solutions containing varying concentrations of purified human serum albumin. The Microalbumin Calibrators have expected values (lot specific) of 1, 2.5, 5, 10, and 20 mg/dL, and the Microalbumin_2 Calibrators have expected values (lot specific) of 1, 4, 10, 20, and 40 mg/dL.

The calibrators (2 mL/vial) are liquid and ready to use. Storage is at 2 - 8°C.

CAUTION! POTENTIAL BIOHAZARD: Contains human source material. While each human serum or plasma donor unit used in the manufacture of this product was tested by FDA-approved methods and found nonreactive for hepatitis B surface antigen (HBsAg), antibody to hepatitis C (HCV), and antibody to HIV-1/2, all products manufactured using human source material should be handled as potentially infectious. Because no test method can offer complete assurance that hepatitis B or C viruses, HIV, or other infectious agents are absent, these products should be handled according to established good laboratory practices.

Statement of Intended Use:

The ADVIA® Chemistry Microalbumin Calibrators are for *in vitro* diagnostic use in the calibration of ADVIA Chemistry systems for the ADVIA® Chemistry Microalbumin method (for quantitation of albumin in human urine).

The ADVIA® Chemistry Microalbumin_2 Calibrators are for *in vitro* diagnostic use in the calibration of ADVIA Chemistry systems for the ADVIA® Chemistry Microalbumin_2 method (for quantitation of albumin in human urine).

Performance:

The traceability, value assignment, and stability of the ADVIA® Chemistry Microalbumin and ADVIA® Chemistry Microalbumin_2 Calibrators have been validated following procedures of Siemens Medical Solutions Diagnostics. These calibrators are substantially equivalent to currently marketed devices with similar intended uses.

Comparison to the Predicate Device:

Similarities and Differences between the devices and the predicate are shown below:

Comparison Table*

	Device #1	Device #2	Predicate
Item	ADVIA® Chemistry Microalbumin Calibrators	ADVIA® Chemistry Microalbumin_2 Calibrators	DCL Microalbumin Multi-Calibrator Set
Intended Use	For *in vitro* diagnostic use in the calibration of ADVIA Chemistry systems for the Microalbumin method (for quantitation of albumin in urine)	For *in vitro* diagnostic use in the calibration of ADVIA Chemistry systems for the Microalbumin_2 method (for quantitation of albumin in urine)	For *in vitro* diagnostic use as a calibrator for the DCL Microalbumin Assay for quantitation of albumin in human urine
Specimen Type (calibrated method)	Human Urine	Human Urine	Human Urine
Matrix	Liquid	Liquid	Liquid
Instructions for Use (Preparation)	The calibrators are ready to use. Mix by inversion at least five (5) times to ensure homogeneity prior to use.	The calibrators are ready to use. Mix by inversion at least five (5) times to ensure homogeneity prior to use.	The calibrators are provided in a ready to use format.
Calibrator Levels	5	5	6
Expected Values	Lot specific: **1, 2.5, 5, 10, and 20 mg/dL**	Lot specific: **1, 4, 10, 20, and 40 mg/dL**	Lot specific: **0.1, 0.5, 1, 5, 10 and 30 mg/dL**
Shelf Life Stability	2 years	2 years	2 years
Open Vial Stability	28 days stored @2-8°C	60 days stored @2-8°C	30 days stored @2-8°C
Standardization	Internal	Internal	Internal

* From Instructions for Use

Conclusions:

The ADVIA® Chemistry Microalbumin Calibrators and ADVIA® Chemistry Microalbumin_2 Calibrators are substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the currently marketed DCL Microalbumin Multi-Calibrator Set (k042243) in intended use, matrix, expected values, and stability.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 5 ˇ 2007

Siemens Medical Solutions Diagnostics
c/o Philip Liu, Manager, Regulatory Affairs & Compliance
551 Benedict Avenue
Tarrytown, NY 10591

Re: k072204
Trade/Device Name: ADVIA® Chemistry Microalbumin Calibrators
ADVIA® Chemistry Microalbumin_2 Calibrators
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator, Multi-Analyte Mixture
Regulatory Class: Class II
Product Code: JIX
Dated: August 6, 2007
Received: August 8, 2007

Dear Mr. Liu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k072204

Device Name(s): ADVIA CHEMISTRY Microalbumin Calibrators
ADVIA CHEMISTRY Microalbumin Calibrators_2 Calibrators

Indications For Use:

The ADVIA® Chemistry Microalbumin Calibrators are for *in vitro* diagnostic use in the calibration of ADVIA Chemistry systems for the ADVIA Chemistry Microalbumin method (this method is used for *in vitro* quantitation of albumin in urine).

The ADVIA® Chemistry Microalbumin_2 Calibrators are for *in vitro* diagnostic use in the calibration of ADVIA Chemistry systems for the ADVIA Chemistry Microalbumin_2 method (this method is used for *in vitro* quantitation of albumin in urine).

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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